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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/708,688 | 03/18/2004 | David L. Vesely | 1372.143.PRC | 2687 |
| 21901 | 7590 | 10/18/2004 | EXAMINER | |
| SMITH & HOPEN PA 15950 BAY VISTA DRIVE SUITE 220 CLEARWATER, FL 33760 | | | TSAY, MARSHA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1653 | |

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/708,688

Applicant(s)

VESELY, DAVID L.

Examiner

Marsha M. Tsay

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>07/01/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending and under examination.

Priority: The instant application was filed on March 18, 2004. This application claims priority to Provisional application 60/320,018, filed March 19, 2003. The priority date is March 19, 2003.

Specification

The disclosure is objected to because of the following informalities: in section [0045], the term "acclminization" should be changed to "acclimatization".

Appropriate correction is required.

Claims 1-10 are objected to because of the following informalities: the claims are improperly numbered. The claims should be numbered sequentially in Arabic numerals in accordance with MPEP 608.01(j). Appropriate correction is required.

Claim 5 is objected to because there is no period at the end of the claim statement.

Claim Objections

Claims 9, 10 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1-4 and 5-8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inhibiting the growth of cancer cells, specifically the pancreatic adenocarcinoma cell line CRL-2119, does not reasonably provide enablement for inhibiting the growth of other types of cancer cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1-10 are drawn to a method of inhibiting the growth of cancer cells comprising the step of contacting the cell with peptide hormone derived from the atrial natriuretic peptide prohormone. The claims are specifically drawn to cancer cells chosen from the group consisting of adenocarcinomas, small cell carcinomas and squamous cell carcinoma. The specification discloses the working example of treating pancreatic adenocarcinoma cancer cells from cell line CRL-2119, in culture and in a mouse model, by administering ANP peptides. It is known that cancer treatment is a complex process that involves, among other factors, the type of cancer and the stage of the cancer. While the specification does provide guidance with respect to treating cancer, it is only directed towards a specific type, pancreatic adenocarcinoma of cell line CRL-2119. Wigle et al. (Wigle et al. 1995 Am J Physiol. 258(5 Pt 2) :H1869-74) teach

the secretion of ANP from small cell lung cancer lines, OS-A and SHP-77. Wigle et al. investigated the secretion of ANP from a number of established lung cancer cell lines and have identified OS-A and SHP-77 as releasing a significant quantity of ANP into the culture medium (p. H1869). Both forms of ANP (aa1-126) and ANP (aa99-126) were detected, therefore SCLC cell lines appear to secrete ANP (aa99-126), the known biologically active, circulating form secreted from the atrial tissue. Wigle et al. teach SCLC cells as stably secreting ANP, while also rapidly proliferating in culture (p. H1873). From these results, it is not clear if ANP peptides can be enabled as an anti-cancer agent for the cancer groups chosen by the Applicant. The ANP peptides may be enabled as a method of inhibiting the growth of pancreatic adenocarcinoma CRL-2119 cells, but it is not definite or clear if it can be used as an agent to treat other types of adenocarcinomas, small cell carcinomas, and squamous cell carcinomas.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, 9-10 are drawn to a target cell. The claims are indefinite because they do not properly define what a target cell is. Claims 9-10 disclose examples of what a target cell can be, but there is no clear and concise definition as to what it is.

Claim 4 is dependent on Claim 1. However, it lacks antecedent basis in Claim 1 because Claim 1 is only drawn to cells.

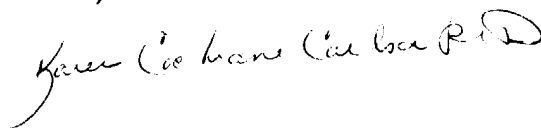
Claim 8 is dependent on Claim 1. However, it lacks antecedent basis in Claim 5 because Claim 5 is only drawn to cells.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

October 12, 2004